

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

The Regents of the University of California,

NO. C 03-05669 JW

Plaintiff,

**SECOND SUPPLEMENTAL CLAIM
CONSTRUCTION ORDER;**

v.

Micro Therapeutics, Inc. and Dendron GmbH,

**ORDER DENYING MOTION FOR
SUMMARY JUDGMENT OF
INVALIDITY BASED ON LACK OF
WRITTEN DESCRIPTION;**

Defendants and Third Party
Plaintiffs,

v.

Boston Scientific Corp. and Target Therapeutics,
Inc.,

**ORDER FINDING CLAIM ARGUABLY
INVALID AND REQUESTING
FURTHER BRIEFING**

Third Party Defendants.

I. INTRODUCTION

Plaintiff The Regents of the University of California ("The Regents" or "Plaintiff") brings this action against Defendants Micro Therapeutics Inc. ("MTI") and its wholly owned subsidiary Dendron GmbH (collectively, "Defendants") for infringement of twelve of The Regents' patents which relate to devices for occluding vascular cavities for the treatment of brain aneurysms.

Presently before the Court is Defendants' Motion for Summary Judgment of Invalidity of the Patents-In-Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2. The Court conducted a hearing on June 5, 2007. On July 9, 2007, the Court issued an order addressing Defendants' motion for summary judgment on the grounds of failure to disclose the best mode requirement and indefiniteness. (See Docket Item No. 789.) This Order addresses Defendants' ground of invalidity

1 based on failure of the patents to satisfy the written description requirement. (Defendants' Motion
2 for Summary Judgment for Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. §
3 112, ¶¶ 1 and 2, hereafter, "Motion," filed under seal; redacted version at Docket Item No. 610.)

4 Defendants move for summary judgment of invalidity of Claims 1- 4 of the '136 Patent on
5 the ground that those claims encompass methods of occlusion other than electrothrombosis and are
6 therefore, invalid for lack of written description.¹ In its consideration of the motion, the Court has
7 determined that further construction of claims is required. This Order gives the Court's additional
8 claim construction, in which it finds a claim arguably indefinite. With respect to the motion for
9 summary judgment, the motion is DENIED, without prejudice to being renewed. The Court gives
10 instructions on the matters which must be addressed if the motion is renewed.

11 **II. STANDARDS**

12 **A. The Principles of Claim Construction**

13 The Court applies the legal standards recited in its previous Claim Construction Orders.

14 **B. The Written Description Requirement**

15 Title 35 U.S.C. § 111 provides that an application for a patent must include a "specification,"
16 which complies with the requirement of § 112. Section 112 requires, *inter alia*, the specification to
17 conclude with the recitation of one or more claims:

18 The specification shall conclude with one or more claims particularly pointing out
19 and distinctly claiming the subject matter which the applicant regards as his
invention.

20 35 U.S.C. § 112, ¶ 2.

21 In addition, § 112 requires that the specification satisfy three separate, but related,
22 requirements: (1) it must contain a "written description" of the invention; (2) enable a person of
23

24 ¹ Defendants move for summary judgment with respect to Claims 1-12. However, Claims 7,
25 8, 9, 10, 11 and 12 include electrothrombosis. Therefore, the Court finds the motion inapplicable to
26 those claims. In addition, because Claims 4 and 5 disclose a method for using electricity to detach
27 the tip from the guidewire, and do not disclose any isolation of the tip from the electricity, the Court
will not consider Claims 4 and 5 to be included in the motion. The parties may file motions at their
option addressing this aspect of Claims 4 and 5.

1 skill in the art to make and use the invention; and (3) if the inventor contemplates one, set forth the
2 best mode for carrying out the invention:

3 The specification shall contain a written description of the invention, and of the manner and
4 process of making and using it, in such full, clear, concise, and exact terms as to enable any
5 person skilled in the art to which it pertains, or with which it is most nearly connected, to
make and use the same, and shall set forth the best mode contemplated by the inventor of
carrying out his invention.

6 35 U.S.C. § 112, ¶ 1; See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004).

7 Although the three requirements are related, the “written description” requirement is distinct
8 and independent from the “enablement” and “best mode requirement.” Univ. of Rochester, 358 F.3d
9 at 922. There have been cases in which the courts have held that a specification met the written
10 description requirement, but nevertheless found that the description was not “enabling.” Id. (citing
11 In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996)). Similarly, there have been cases holding a
12 specification “enabling” of the invention as disclosed, but holding that it did not contain an adequate
13 “written description” of other parts of the invention. Id. (citing In re DiLeone, 436 F.2d 1404, 1405
14 (C.C.P.A. 1971)).

15 The written description requirement applies to the specification which is included with the
16 original patent application and continues to apply if the claims are amended during prosecution of
17 the patent. 35 U.S.C. § 112, ¶¶ 1 and 2. To comply with the written description requirement, the
18 applicant must describe elsewhere in the specification the invention claimed at the end of the
19 specification, with all its essential elements. Lockwood v. American Airlines, Inc., 107 F.3d 1565,
20 1572 (Fed. Cir. 1997). The failure of the specification to describe expressly or inherently a single
21 essential element is sufficient to invalidate a claim. See e.g. Bilstad v. Wakaloupoulos, 386 F.3d
22 1116 (Fed. Cir. 2004).

23 Whether a specification complies with the written description requirement is a question of
24 fact. Lizardtech Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373 (Fed. Cir. 2006); Union Oil v.
25 Atl. Richfield Co., 208 F.3d 989, 996 (Fed. Cir. 2000). The factual issue is whether the disclosure in
26 the specification reasonably conveys to a person skilled in the art that the inventor had possession of
27

1 the claimed invention at the time the application was filed. Thus, the factual analysis begins with
2 the claim, properly construed. The claim determines the scope of the claimed invention. To satisfy
3 the written description requirement, the inventor must “describe” the claimed invention, using such
4 descriptive means as words, structures, figures, diagrams, formulas, etc., sufficiently to convey to a
5 skilled artisan what is claimed. Lockwood, 107 F.3d at 1572.

6 The issue of whether the specification satisfies the written description requirement is
7 frequently raised in interference or infringement actions in which an inventor has disclosed a species
8 in the original specification and has later amended the claim to cover a genus.² See In re Smythe,
9 480 F.2d 1376, 1382 (C.C.P.A. 1973). However, there is no general proposition in patent law that
10 the written description requirement is violated if the original description is narrower than a broad
11 claim. Id. Each case must be decided on its own facts. However, when a narrow disclosure is made
12 in the original written description of the invention, and the claim is amended to broaden the scope of
13 the claim, upon challenge, courts examine the written description to determine if a skilled artisan in
14 that particular field would find from what is stated in the specification that the inventor was in
15 possession of the broader claim at the time of the original application. See In re John P. Curtis, 354
16 F.3d at 1355-1356. Disclosure of a species in the original written description may be sufficient or
17 insufficient to support a later amendment to broaden the claim to cover the genus depending on the
18 facts of the case. Id.; Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir.
19 1997); Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582 (Fed. Cir.
20 1996).

21 Some of the factors which courts have used to decide if the written description requirement
22 has been met are the following:

24 ² The issue of whether the written description requirement has been met can also arise when
25 a genus claim is amended to claim a specific species. In such a case, the issue is whether the written
26 description of a genus which includes thousands of species would convey to a person of skill in the
27 art that the inventor has possession of the specific species sought to be captured by the amendment.
See In re John P. Curtis, 354 F.3d 1347 (Fed. Cir. 2004).

1 1. Whether the written description provides that it is because of their **properties and**
2 **functions** that particular elements or steps are disclosed under circumstances which would
3 immediately convey to a person skilled in the art that the invention includes the broader group which
4 the inventor seeks to capture in the amended claim. See In re Smythe, 480 F.2d at 1384.
5 (Disclosure of the properties and functions of “air or other gas” as a segmentizing medium held
6 sufficient to suggest to skilled artisan that invention includes “inert fluid” broadly.)

7 2. Whether the original narrow written description, lists **members of a group** and a skilled
8 artisan would know from the list that the invention would apply equally to other undisclosed, **well-**
9 **known** members of the group which the inventor is seeking to capture by an amendment. See
10 Bilstad, 386 F.3d at 1117.

11 3. Whether the subject matter for which inclusion is being sought under a broad amended
12 claim includes species which were regarded by skilled artisans as being **unpredictable in**
13 **performance** as compared to those which were disclosed in the narrow original written description.
14 See In re Curtis, 354 F.3d at 1355.

15 4. Whether the original written description attributes **unique properties** to the listed
16 embodiments which are different from the properties of other members of the genus. Id. at 1357.

17 5. Whether in the original application the inventor **embraced or criticized** the process for
18 which inclusion is being sought under an amendment. See Tronzo v. Biomet, 156 F.3d 1154, 1159
19 (Fed. Cir. 1998).

20 **C. Summary Judgment of Invalidity Under § 112, ¶¶ 1 and 2**

21 As set out above, compliance with the written description requirement is a question of fact.
22 Lizardtech Inc., 433 F.3d at 1375; Union Oil, 208 F.3d at 996. Summary judgment is proper “if the
23 pleadings, depositions, answers to interrogatories, and admissions on file, together with the
24 affidavits, if any, show that there is no genuine issue as to any material fact and that the moving
25 party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The purpose of summary
26 judgment “is to isolate and dispose of factually unsupported claims or defenses.” Celotex v. Catrett,

1 477 U.S. 317, 323-24 (1986). The moving party “always bears the initial responsibility of informing
2 the district court of the basis for its motion, and identifying the evidence which it believes
3 demonstrates the absence of a genuine issue of material fact.” Id. at 323. The non-moving party
4 must then identify specific facts “that might affect the outcome of the suit under the governing law,”
5 thus establishing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e).

6 When evaluating a motion for summary judgment, the court views the evidence through the
7 prism of the evidentiary standard of proof that would pertain at trial. Anderson v. Liberty Lobby
8 Inc., 477 U.S. 242, 255 (1986). The court draws all reasonable inferences in favor of the non-
9 moving party, including questions of credibility and of the weight that particular evidence is
10 accorded. See, e.g. Masson v. New Yorker Magazine, Inc., 501 U.S. 496, 520 (1992). The court
11 determines whether the non-moving party’s “specific facts,” coupled with disputed background or
12 contextual facts, are such that a reasonable jury might return a verdict for the non-moving party.
13 T.W. Elec. Serv., 809 F.2d at 631. In such a case, summary judgment is inappropriate. Anderson,
14 477 U.S. at 248. However, where a rational trier of fact could not find for the non-moving party
15 based on the record as a whole, there is no “genuine issue for trial.” Matsushita, 475 U.S. at 587.

16 Generally, an issued patent enjoys a presumption of validity that can be overcome only by
17 clear and convincing evidence of invalidity. U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554,
18 1563 (Fed. Cir. 1997). Thus, a party seeking to invalidate a patent by a motion for summary
19 judgment must submit clear and convincing evidence of invalidity. Eli Lilly & Co. v. Barr Labs.,
20 Inc., 251 F.3d 955, 962 (Fed. Cir. 2001). Further, summary judgment of invalidity of a patent claim
21 on the ground that the patent specification fails to satisfy the written description requirement is
22 appropriate when there is no genuine dispute about the material facts, and on the basis of those facts,
23 the specification is inadequate as a matter of law. Fed. Rule Civ.P. 56(c); Enzo Biochem v. Gen-
24 Probe Inc., 323 F.3d 956, 963 (Fed Cir. 2002).

III. DISCUSSION

Defendants move for summary judgment of invalidity on the ground that the specification does not satisfy the written description requirement with respect to Claims 1-4 of the '136 Patent.

Defendants make the following contentions: Originally, the inventors applied for a patent for an apparatus and method for endovascular electrothrombosis. Each of the claims in the original application related to electrothrombosis. The written description submitted with the '717 Application described a method for forming a thrombus using electrothrombosis. Approximately one year later, the inventors amended Claim 1 to broaden it to cover "occlusion" by "thrombus," which includes every process for forming a thrombus. Still later, the inventors amended Claim 1 to broaden it to cover "occlusion," thus removing any requirement that the occlusive object be a thrombus. However, the written description was never amended. Thus, the claims at issue cover the genus "occlusion" while the written description only discloses methods for the species "electrothrombosis." Defendants contend that this divergence between the narrow written description and the broad Claim 1, and dependent Claims 2 - 4, invalidates these claims. In addition, Defendants contend that the only process of which Plaintiff had possession was electrothrombosis.

As stated above, an analysis of whether a specification meets the written description requirement begins with the claim, properly construed. Accordingly, the Court proceeds to reexamine its construction of Claim 1 of the '136 Patent.

A. Modification of the Court's Previous Construction of Claim 1 of the '136 Patent

On March 2, 2007 and on June 26, 2007, the Court construed certain words and phrases of Claim 1 of the '136 Patent.³ The contentions made by the parties in support and opposition to Defendants' motion for summary judgment have persuaded the Court that further construction of Claim 1 is necessary. The contentions made by the parties highlight a dispute over the proper construction of the following claim element: "disposing a distal tip of said guide wire into said

³ (See Supplemental Claim Construction Order, Docket Item No. 482; Third Claim Construction Order, Docket Item No. 751.)

1 vascular cavity to form said occlusion within said vascular cavity about said distal tip.”
 2 Specifically, there is a dispute over the word “disposing a distal tip” and the phrase “about said
 3 distal tip.” In addition, there is a dispute over the meaning of the phrase “any thrombus” in the
 4 “whereby” clause and whether the “whereby” clause is limiting in that it requires forming a
 5 thrombus as a necessary element of the method.

6 Claim 1 of the ‘136 Patent provides:⁴

7 A method for forming an occlusion within a vascular cavity having blood disposed
 8 therein comprising the steps of:

9 endovascularly disposing a guidewire near an endovascular
 10 opening into said vascular cavity;

11 **disposing a distal tip of said guide wire into said vascular
 12 cavity to form said occlusion within said vascular cavity about said
 13 distal tip;** and

14 detaching said distal tip from said guidewire to leave said
 15 distal tip within said vascular cavity and said occlusion being formed
 16 within said vascular cavity,

17 **whereby said vascular cavity is occluded by said distal tip,
 18 and any thrombus formed by use of said tip.**

19 **1. “disposing”**

20 The method of Claim 1 is disclosed as comprising three steps, two of which use the word
 21 “disposing:” (1) endovascularly disposing a guide wire near an endovascular opening; (2) disposing
 22 a tip into the vascular cavity; and (3) detaching the distal tip. The word “disposing” is a commonly
 23 used word with many definitions, the applicability of each definition depends on the context in
 24 which it is used. In Claim 1, the word “disposing” is used to disclose the steps of placing guidewire
 25 near an opening to a vascular cavity and the step of inserting the tip into a vascular cavity for the
 26 purpose of forming an occlusion within the cavity about the tip:

27 endovascularly **disposing a guidewire near an endovascular opening** into
 28 said vascular cavity;

disposing a distal tip of said guide wire into said vascular cavity to form
 said occlusion within said vascular cavity about said distal tip

⁴ Unless otherwise indicated, all bold typeface is added by the Court for emphasis.

From the use of the word in Claim 1, one of ordinary skill in the art would understand that the inventors are using the word “disposing” with one of its common meanings, i.e., a manipulative step of placing an object in a location or position.

Further, in dependent Claim 2, the inventors also use “disposing” to mean a manipulative step of “substantially occupying” the vascular cavity, i.e., to put more of the tip or a longer or larger tip into the cavity:

The step of **disposing** the distal tip in the vascular cavity further comprises the step of substantially occupying the vascular cavity with the distal tip.

Accordingly, the Court construes the word, “**disposing**” as it is used in Claims 1-4⁵ to mean “**a manipulative step in which an object is placed in a particular location or position.**”⁶

2. “about said distal tip”

In the second step, “said occlusion” is formed “about said distal tip.” Nothing in the specification, including the claims, indicates explicitly or implicitly that the inventors intended to impart a novel meaning to “about said tip.” There is no evidence that “about said tip” has a peculiar meaning in the field of art encompassed by the ‘136 Patent. Therefore, the Court concludes that the ordinary and customary meaning attributed to this term by those of ordinary skill in the art at the

⁵ The word “disposing” is also used in Claim 8. However, the Court does not apply this construction to Claim 8 because the Court will discuss Claim 8's arguable indefiniteness in Section C.

⁶ Elsewhere in the specification, the inventors use the related term “disposed” in their description of an embodiment:

Once **disposed out of the tip** of the microcatheter, secondary coil 28 forms the shape shown in FIG. 1 and may similarly be loosely deformed to the interior shape of the aneurysm.

(‘136 Patent, Col. 6:44-47.)

They also use “disposed” to describe a prior art reference:
O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter.
The tip is adhesively bonded to a optic fiber **disposed through the microcatheter.**

(‘136 Patent, Col. 3:23-25.)

1 time of the invention is a widely accepted meaning. Phillips v. AWH Corp., 363 F.3d 1207, 1314
2 (Fed. Cir. 2004).

3 Accordingly, the Court construes the phrase **“about said distal tip”** to mean **“on or around**
4 **the distal tip.”**

5 **3. “to form said occlusion”**

6 The “disposing into” step requires that an occlusion be formed. The step does not state what
7 object constitutes the occlusion, only that it be formed “about” the distal tip. Thus, the occlusion
8 which is “formed” cannot be the tip itself, because it cannot “form” on or about itself.

9 A person of skill in the art would understand from the “whereby” clause that the occlusion is
10 the tip and “any thrombus.” Previously, the Court has found that the whereby clause is limiting in
11 that it supplies an essential element, namely, the occlusion consists of two things: (1) the tip and (2)
12 “any thrombus.”

13 Accordingly, the Court finds that forming an occlusion on or around the tip is a necessary
14 element of the method.

15 **4. “any thrombus”**

16 The issue now becomes whether the phrase “any thrombus” means “with or without a
17 thrombus.” The word “any” is a common term which variously means: “One or some, regardless of
18 kind, quantity or number; one or another selected at random, one or another without restriction or
19 exception; the whole amount of; all [I will turn over any profit]; an indeterminate number or
20 amount.” See Webster’s New Twentieth Century Dictionary, 83 (2d ed. 1983). Since formation of
21 an occlusion is required by the “disposing into” step, and because the “whereby” clause requires that
22 “any thrombus” be included in the occluding objects, the Court concludes that the phrase **“any**
23 **thrombus”** means **“a thrombus irrespective of its size.”**

24 However, there is still the issue of the difference between the broad language of the
25 “disposing into step” (“said occlusion . . . about said tip”) and the narrow language of the “whereby”
26
27
28

1 clause (“any thrombus”).⁷ On the one hand, the broad language of the “disposing into step” would
2 permit any form of occlusion. For example, the invention could be practiced using any embolizing
3 agent, which forms about the inserted tip. Thus, balloon embolization, thermal coagulation of blood,
4 isobutylcyanoacrylate (ICBA) polymerization, as well as thrombosis would all be occlusions which
5 could satisfy the step, as long as each could be formed “about” the tip. On the other hand, the
6 “whereby” clause only discloses “any thrombus” as part of the occlusion. However, although the
7 Court has found that the “whereby” clause is limiting in one respect, the Court does not find that the
8 “whereby” clause limits the method of occlusion to a thrombus.

9 Accordingly, the Court now construes the phrase “disposing a distal tip of said guidewire
10 into said vascular cavity to form said occlusion within said vascular cavity about said distal tip” to
11 mean: **“placing the distal tip of a guidewire into a vascular cavity to form a blockage in the**
12 **vascular cavity. The blockage is formed on or around the distal tip.”**

13 Having now construed the words and phrases of Claim 1, the scope of the claim is clear from
14 its language. The inventors claim as their invention a method for occluding a vascular cavity by a
15 blockage formed on or around a distal tip. The claim is broad enough to cover a thrombus formed
16 from the mere presence of the distal tip, i.e., mechanical thrombosis or from using the distal tip in
17 some manipulative step, e.g., electrothrombosis.⁸ In other words, as construed by the Court, Claim 1
18 covers all processes for endovascular occlusion, including all processes for endovascular thrombosis
19 formation in which the occlusion is formed on and around a detachable distal tip.

20 The issue becomes whether the written description adequately describes that invention.
21 Defendants contend that it does not. Defendants point to the narrow written description and a
22 statement made by the inventors to the examiner that other occlusions were “possible” as proof of
23

24 ⁷ The Court notes that during prosecution, the inventors amended the claim to eliminate
25 “thrombus” from the Preamble and steps of the Claim, but left “any thrombus” in the “whereby”
clause.

26 ⁸ The Claim does not cover mechanical object occlusion, such as a balloon, because in the
27 processes described in the specification, the mechanical object **is** the occlusion and nothing is
“formed” about the tip.

inadequacy. The Court proceeds to examine whether the original claim, the subsequent amendment, and the current written description support a broad reading of Claim 1 of the '136 Patent.

B. Analysis of Claim 1 of the '136 Patent

1. The Original '717 Application

On March 13, 1990, the inventors filed the '717 Application which was later issued as the '136 Patent. With respect to matters pertinent to this motion⁹, the "claim" was a method for using "an electrical signal" to form a thrombus within a vascular cavity:

I claim:

(1) A method for forming a thrombus within a vascular cavity having blood disposed therein comprising the steps of:
 endovascularly disposing a guidewire near an endovascular opening into said vascular cavity;
 disposing a distal tip of said guidewire into said vascular cavity;
 applying a first electrical signal to said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip; and
 electrolytically detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said thrombus electrically formed within said vascular cavity,
 whereby electrical formation of a thrombus is completely endovascularly formed.

(Exhibit UCR 6254.)

Although the inventors described other prior art methods for occluding vascular cavities, electrothrombosis was the only method for forming a thrombus described in the original claims and the original written description of the invention. Significantly, electrothrombosis was described in each embodiment of the invention.¹⁰

⁹ The Claim covered other aspects to the invention such as endovascular disposing of a guidewire and detaching the distal tip. Whether these other aspects were supported by the written description is not being considered in this Order.

¹⁰ FIG. 1 is an enlarged view of a first embodiment. . .after placement of secondary coil 28 within the interior of the aneurysm, a direct current is applied . . .The positive charge on the secondary coil 28 within the cavity of the aneurysm causes a thrombus to form within the aneurysm by electrothrombosis.

* * *

FIG. 2 illustrates an enlarged partially cross-sectional view a second embodiment of the invention. . . The embodiment of FIG. 2 is utilized in exactly the same manner as described above in connection with FIG. 1 to form a thrombic mass within an aneurysm or other vascular cavity.

The Court finds that the original claims and written description limited Claim 1 to electrothrombosis.

2. The April 12, 1991 Preliminary Amendment to the '717 Application

On April 9, 1991, the applicants submitted a "Preliminary Amendment" to the '717 Application as follows:¹¹

Please amend the claims as follows:

1. (once amended) A method for forming a thrombus within a vascular cavity having blood disposed therein comprising the steps of:
 - endovascularly disposing a guidewire near an endovascular opening into said vascular cavity;
 - disposing a distal tip of said guidewire into said vascular cavity[; applying a first electrical signal to] said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip;¹² and
 - electrolytically detaching said distal tip from said guidewire to leave said distal tip within said vascular cavity and said thrombus electrically formed within said vascular cavity,
 - whereby [electrical] formation of a thrombus is completely endovascularly formed.

In the submission, the inventors eliminated the "applying a first electrical signal" step altogether. As amended, "disposing a distal tip" became the only step recited as necessary "to form a thrombus . . . about said distal tip." It is clear that the amendment broadened Claim 1 from a claim limited to electrothrombosis to a claim for any thrombosis formed on or around a distal tip. Although there were subsequent amendments, the same broad scope is present in Claims 1-4, as

* * *

Turn now to the third embodiment of the invention as shown in FIG. 3. . . A positive electric current of approximately 0.01 to 2 milliamps at 0.1 - 6 volts is applied to guidewire 42 to form the thrombus.

¹¹ Symbols and punctuation are from the original.

¹² The Court notes that as amended the "disposing step" provides: "disposing a distal tip of said guidewire into said vascular cavity said distal tip within said vascular cavity to form a thrombus within said vascular cavity about said distal tip." On April 15, 1991, the inventors made a Revised Preliminary Amendment. However, the "disposing step" was left unchanged. On August 12, 1991, the inventors filed an Amendment; the Amendment removed the duplicative language. The "disposing step" as amended, provides: "disposing a distal tip of said guidewire into said vascular cavity [said distal tip within said vascular cavity] to form [a thrombus] said occlusion within said vascular cavity about said distal tip."

1 issued. Accordingly, the Court finds that the April 12, 1991 Preliminary Amendment, while
2 continuing to rely on the original written description, broadened the scope of Claim 1 when the
3 inventors eliminated electrothrombosis as a limitation.

4 **3. The Prosecution of the ‘136 Patent**

5 In the prosecution of the ‘136 Patent, the inventors amended Claim 1 to encompass occlusion
6 forming processes that did not depend upon electricity. For a claim to be valid, the written
7 description must describe the process or processes which would convey to a person of skill in the art
8 that at the time of the original application, the inventors were in possession of such a process.

9 The written description clearly describes electrothrombosis. In addition, in their discussion
10 of prior art, the inventors discuss other occlusion processes known in the art. The Court finds that
11 except for a description of prior art methods, the specification only describes electrothrombosis in
12 the description of the invention. The issue becomes whether the disclosure of electrothrombosis in
13 the description of the invention and of other occlusion processes in the prior art, would convey to a
14 person of skill in the art that the invention includes the prior art process or any other unnamed
15 process. Before discussing the evidence with respect to what the prior art would convey to a person
16 of skill in the art, the Court describes and categorizes the prior art processes.

17 In the “Background” section of the specification, the inventors list four types of occlusion
18 processes; the Court examines them in turn:

19 **a. Mechanical Object Occlusion**

20 The Court defines “mechanical object occlusion” as a method for occluding a vascular cavity
21 by inserting into the cavity an object or tool. The cavity is blocked, occupied or otherwise closed off
22 primarily by the mechanical object, itself, as opposed to some chemical change in the body brought
23 about from using the tool.

24 Under the section of the application entitled “Background of the Invention,” the inventors
25 describe methods for “mechanical object occlusion” by mechanically tying off the cavity:

26 The extravascular approach is comprised of surgery or microsurgery of the aneurysm
27 or treatment site for the purpose of preserving the parent artery. This treatment is

1 common with intracranial berry aneurysms. The methodology comprises the step of
2 **clipping the neck of the aneurysm, performing a sutureligation of the neck, or**
3 **wrapping the entire aneurysm.** Each of these surgical procedures is performed by
4 intrusive invasion into the body and performed from outside the aneurysm or target
5 site. General anesthesia, craniotomy, brain retraction and arachnoid dissection around
6 the neck of the aneurysm and placement of a clip are typically required in these
7 surgical procedures. Surgical treatment of vascular intracranial aneurysm can expect
8 a mortality rate of 4-8% with a morbidity rate of 18-20%. Because of the mortality
9 and morbidity rate expected, the surgical procedure is often delayed while waiting for
10 the best surgical time with the result that an additional percentage of patients will die
11 from the underlying disease or defect prior to surgery. For this reason the prior art
12 has sought alternative means of treatment.

13 Another "mechanical object occlusion" method described in the background section is using
14 a balloon to occlude a vascular cavity:

15 In the endovascular approach, the interior of the aneurysm is entered through the use
16 of a microcatheter. Recently developed microcatheters, such as those shown by
17 Engleson, "Catheter Guidewire", U.S. Pat. No. 4,884,579 and as described in
18 Engleson, "Catheter for Guidewire Tracking", U.S. Pat. No. 4,739,768 (1988), allow
19 navigation into the cerebral arteries and entry into a cranial aneurysm.

20 In such procedures **a balloon** is typically attached to the end of the microcatheter and
21 **it is possible to introduce the balloon into the aneurysm, inflate it, and detach it,**
22 **leaving it to occlude the sac and neck with preservation of the parent artery.**
23 While endovascular balloon embolization of berry aneurysms is an attractive method
24 in situations where an extravascular surgical approach is difficult, inflation of a
25 balloon into the aneurysm carries some risk of aneurysm rupture due to possible over-
26 distention of portions of the sac and due to the traction produced while detaching the
27 balloon.

28 While remedial procedures exist for treating a ruptured aneurysm during classical
extravascular surgery, no satisfactory methodology exists if the aneurysm breaks
during an endovascular balloon embolization.

Furthermore, an ideal embolizing agent should adapt itself to the irregular shape of
the internal walls of the aneurysm. On the contrary, in a balloon embolization the
aneurysmal wall must conform to the shape of the balloon. This may not lead to a
satisfactory result and further increases the risk of rupture.

A final method for occluding a vascular cavity which is discussed in the background section
of the specification is liquid adhesive polymerization. Although the occlusive mass is described as
being formed on contact with blood, it is the polymer mass which occludes the cavity, not a
chemical change in the blood caused by the adhesive:

The prior art has also devised the use of a liquid adhesive, isobutylcyanoacrylate
(IBCA) which polymerizes rapidly on contact with blood to form a firm mass. The
liquid adhesive is injected into the aneurysm by puncturing the sac with a small

needle. In order to avoid spillage into the parent artery during IBCA injection, blood flow through the parent artery must be momentarily reduced or interrupted. Alternatively, an inflated balloon¹³ may be placed in the artery at the level of the neck of the aneurysm for injection. In addition to the risks caused by temporary blockage of the parent artery, the risks of seepage of such a polymerizing adhesive into the parent artery exists, if it is not completely blocked with consequent occlusion of the artery.

Mechanical object occlusion does not involve formation of a thrombus.

b. Catalytic thrombosis

The Court is using the phrase "catalytic thrombosis" to describe methods for occluding a vascular cavity by using a catalyst to cause or to accelerate formation of a thrombus. The inventors describe two procedures which the Court characterizes as "catalytic thrombosis." The first is electrothrombosis:

In the use of **electrothrombosis** for extra-intravascular treatment the tip of a positively charged electrode is inserted surgically into the interior of the aneurysm. An application of the positive charge attracts white blood cells, red blood cells, platelets and fibrinogen which are typically negatively charged at the normal pH of the blood. The **thrombic mass is then formed in the aneurysm about the tip.** Thereafter, the tip is removed. See Mullan, "Experiences with Surgical Thrombosis of Intracranial Berry Aneurysms and Carotid Cavernous Fistulas", J. Neurosurg., Vol. 41, December 1974; Hosobuchi, "Electrothrombosis Carotid-Cavernous Fistula", J. Neurosurg., Vol. 42, January 1975; Araki et al., "Electrically Induced Thrombosis for the Treatment of Intracranial Aneurysms and Angiomas", Excerpta Medica International Congress Series, Amsterdam 1965, Vol. 110, 651-654; Sawyer et al., "Bio-Electric Phenomena as an Etiological Factor in Intravascular Thrombosis", Am. J. Physiol., Vol. 175, 103-107 (1953); J. Piton et al., "Selective Vascular Thrombosis Induced by a Direct Electrical Current; Animal Experiments", J. Neuroradiology, Vol. 5, pages 139-152 (1978). However, each of these techniques involves some type of intrusive procedure to approach the aneurysm from the exterior of the body.

The second catalytic thrombotic process described by the inventors is ferro-magnetic thrombosis:

Ferromagnetic thrombosis in the prior art in extra-intravascular treatments comprises the stereotactic placement of a magnetic probe against the sac of the aneurysm followed by **injection into the aneurysm by an injecting needle of iron microspheres. Aggregation of the microspheres through the extravascular magnet is followed by interneuysmatic thrombus.** This treatment has not been

¹³ Although this prior art method uses a balloon, it is different from using a balloon in "Mechanical Object Occlusion" because the balloon is not being used to fill the vascular cavity and thus occlude it. The balloon is being used to stop blood flow in the vessel in order to limit the polymerization to the blood in the vascular cavity.

entirely successful because of the risk of fragmentation of the metallic thrombus when the extravascular magnet is removed. Suspension of the iron powder in methyl methacrylate has been used to prevent fragmentation. The treatment has not been favored, because of the need to puncture the aneurysm, the risk of occlusion of the parent artery, the use of unusual and expensive equipment, the need for a craniectomy and general anesthesia, and the necessity to penetrate cerebral tissue to reach the aneurysm.

c. Thermal Coagulation

The inventors differentiate methods which cause the blood to form a thrombus from those using heat which cause the blood to coagulate. Therefore, the Court characterizes any methods using heat as “thermal coagulation.”¹⁴

Endovascular **coagulation of blood** is also well known in the art and a device using **laser optically generated heat** is shown by O'Reilly, "Optical Fiber with Attachable Metallic Tip for Intravascular Laser Coagulation of Arteries, Veins, Aneurysms, Vascular Malformation and Arteriovenous Fistulas", U.S. Pat. No. 4,735,201 (1988). See also, O'Reilly et al., "Laser Induced Thermal Occlusion of Berry Aneurysms: Initial Experimental Results", Radiology, Vol. 171, No. 2, pages 471-74 (1989). O'Reilly places a tip into an aneurysm by means of an endovascular microcatheter. The tip is adhesively bonded to a optic fiber disposed through the microcatheter. Optical energy is transmitted along the optic fiber from a remote laser at the proximal end of the microcatheter. **The optical energy heats the tip to cauterize the tissue surrounding the neck of the aneurysm or other vascular opening to be occluded.** The catheter is provided with a balloon located on or adjacent to its distal end to cut off blood flow to the site to be cauterized and occluded. Normally, the blood flow would carry away the heat at the catheter tip, thereby preventing cauterization. The heat in the tip also serves to melt the adhesive used to secure the tip to the distal end of the optical fiber. If all goes well, the tip can be separated from the optical fiber and left in place in the neck of the aneurysm, provided that the cauterization is complete at the same time as the hot melt adhesive melts.

d. Mechanical Thrombosis

The Court is using the phrase “mechanical thrombosis” to describe methods for occluding a vascular cavity by inserting a thrombogenic material, which, because of its presence, causes formation of a thrombus. In the background section, the inventors discussed a method which the Court places in this category:

¹⁴ Although this prior art method uses a balloon, this is different from the balloon used in “Mechanical Object Occlusion” because the balloon is not being used to treat the vascular cavity by occluding it. The balloon is being used to stop blood flow in the vessel in order to allow the tip to reach an effective temperature.

1 Still further, the prior art has utilized an air gun to **inject hog hair through the**
 2 **aneurysm wall to induce internal thrombosis**. The success of this procedure
 3 involves exposing the aneurysm sufficiently to allow air gun injection and has not
 4 been convincingly shown as successful for thrombic formations.

5 The specification does not describe the hog hair method any further. It is described as a method
 6 which has not been convincingly shown as effective for thrombic formation.

7 **4. Applying the Evidence to the Four Types of Occlusion Processes**

8 To determine whether Defendants have proved by clear and convincing evidence that the
 9 written description is inadequate to convey to a person of skill in the art that the invention covers
 10 one or more of the prior art processes or to an unlisted process, the Court applies the evidence
 11 submitted to the four types of occlusion processes discussed above.

12 Defendants have addressed some but not all of the processes. For example, Defendants have
 13 submitted the declaration of Dr. Donald Larsen which provides:

14 For many years prior to the filing of the application for the '136 patent in 1990,
 15 investigators had embolized vascular cavities with a variety of embolic materials,
 16 including straight and coiled wires. Using both invasive and relatively noninvasive
 (e.g., endovascular) approaches, occlusion was effected through both mechanical and
 electrothrombotic means . . . Platinum wires were used because of their
 thrombogenicity. . . Thrombogenicity of metal can be enhanced by using an electrical
 current, by combining the wire with fabric strands, or by "packing" multiple wires
 into the vascular structure.¹⁵

17 This excerpt appears to describe what the Court has characterized as mechanical object occlusion
 18 and mechanical thrombosis. However, it is unclear to the Court whether Dr. Larsen is stating that
 19 skilled artisans would understand the specification to include the variety of embolic materials and
 20 associated processes.

21 In response, Plaintiffs have submitted the declaration of Dr. Gary Nesbit, which provides,
 22 *inter alia*:

23 . . . [I]t is my opinion that a person of ordinary skill would recognize that filling or
 24 substantially filling a cavity (such as an aneurysm) with a long and pliable distal tip
 such as is shown in originally-filed figures 4 and 5 would necessarily result in

25
 26 ¹⁵ (Declaration of Gabrielle E. Bina, In Support of Defendants' Motion for Summary
 27 Judgment of Invalidity, Ex. 25, Expert Report of Donald Larsen, M.D., quoting in part from Yang
 reference, Docket Item No. 611.)

1 mechanical occlusion of the vascular cavity. This is so because a person of ordinary
 2 skill would know that by putting these types of materials into a cavity such as an
 3 aneurysm, the flow of blood into the cavity would slow. thus, for example, if one
 were to place the coil described and depicted in the specification in an aneurysm, but
 did not apply current to it, it would still slow the flow of blood.¹⁶

4 It is unclear to the Court whether Dr. Nesbit is stating that a skilled artisan would understand that the
 5 specification and drawings describe mechanical object occlusion or mechanical thrombosis. The
 6 Court would find Dr. Nesbit's declaration more helpful if it were to categorize the occlusion
 7 processes in the same way the Court has.

8 In sum, the Court finds that the reference to mechanical thrombosis in the "background"
 9 section of the specification creates a genuine factual dispute as to whether one skilled in the art
 10 would understand from that reference that mechanical thrombosis was being included in the subject
 11 matter of the invention. Accordingly, the Court DENIES Defendants' motion for summary
 12 judgment of invalidity based on lack of written description without prejudice.

13 However, if the parties are inclined to bring this written description issue back before the
 14 Court, the evidence, expert declarations and arguments should be organized in a fashion which
 15 addresses the following:¹⁷

- 16 (1) Would a person of skill in the art conclude or not conclude that a process, which is
 17 covered by a broad claim but which is not described in the written description, is
 nevertheless supported by the written description because the written description
 18 conveys that the reason a process is described in the written description is due to its
properties and functions and a skilled artisan would immediately know from the
 listed process that an unlisted process is also covered?
- 19 (2) Is the process which is described in the written description a **member or not a**
 20 **member of a well-recognized group** such that a skilled artisan would know from the
 listed process that the invention applies equally to another member of the group?
- 21 (3) Is a process which is not described in the written description but which an inventor
 22 seeks to have included in the claim regarded by skilled artisans as being **equally**

23
 24 ¹⁶ (Declaration of Dr. Gary Nesbit in Support of Plaintiff's Opposition to Defendants'
 25 Motion for Summary Judgment of Invalidity for Failure to Comply With 35 § 112 ¶¶ 1 and 2 ¶ 13,
 Docket Item No. 646.)

26 ¹⁷ If the parties choose not to bring the issue back to the Court, they are advised that the
 27 Court will include these factors in its instructions to the jury on deciding invalidity on the ground of
 inadequate written description.

predictable or not in performance as compared to a process which is disclosed in the written description?

- (4) Does the original written description attribute or not attribute **unique properties** to the process which is described, and would a person of skill in the art conclude that the undescribed process shares those same unique properties?
- (5) Is the undescribed process which the inventor seeks to include in the invention a prior art which the inventor **criticized** in a manner which would lead a skilled artisan to conclude that the inventor intended or did not intend to include the process in the coverage of the invention?
- (6) If the inventor admits that at the time of the original application he or she was **not aware** of a later realized species¹⁸ (but one which is known in the art generally), and they only describe species of which they are personally aware in the written description, what significance, if any, does such an admission have on a person of ordinary skill in the art whether the later realized species should be considered as part of the invention if upon realization of the species the inventor later broaden his or her claim to capture a genus which includes all species?¹⁹

C. Claim 8 of the '136 Patent

In construing Claim 1, the Court turned its attention to Claim 8 of the '136 because the word "disposing" is also used in Claim 8. The Court now turns to Claim 8 to examine whether it meets the definiteness requirement.

¹⁸ Defendants have produced evidence that in 1991, at the time of the amendment, the inventors speculated that their method could be practiced using mechanical thrombosis: Claim 1, 8 and 12 have been amended to claim an apparatus and method for formation of thrombus which is not dependent on the mechanism of electrothrombic formation. **It is possible that the mechanical presence of the distal tip may be enough to initiate formation of thrombus.** The amendment does not affect the election which has been made.

¹⁹ This may be a mixed question of law and fact. In this case, if the reason the inventors were speculating in April of 1991, about whether the process might work in the absence of electricity is because they were not in possession of a method without electricity, this might require invalidating the claim as a matter of law, unless the patent law allows inventors to claim an invention of greater scope than that of which they are personally aware. In other words, if it were known in the art that a thrombus can be formed in the absence of electricity, but the inventors did not know of such processes when they file their application, and hence did not describe them in the written description. If during prosecution, the inventors began to speculate that these other processes might exist and, based on that speculation the inventors broaden their claim but failed to amend their written description, are the inventors entitled to claim the processes unknown to them but known to the art within the scope of the invention?

1 A determination as to whether a patent claim meets the definiteness requirement is a question
2 of law to be decided by the court in performance of its duty as the construer of patent claims.

3 Bancorp Services, L.L.C. v. Hartford Life Insurance Co., 359 F.3d 1367, 1371 (Fed. Cir. 2004).

4 Claim 8 of the '136 Patent provides:

5 The method of claim 1 wherein said step of disposing said distal tip comprises **the**
6 **step of applying an electrical signal** to said distal tip to form said thrombus by
applying a positive direct current for a first predetermined time period.

7 There are two ways to interpret Claim 8, i.e., a modification of the “disposing step,” or a
8 substitution of the “applying an electrical signal step”; however, the Court finds that adopting either
9 interpretations would present structural problems.

10 First, Claim 8 may be interpreted as a step which is **added to** the “disposing step” of Claim
11 1. Under this interpretation, the phrase in Claim 8, “wherein said step of disposing said distal tip
12 comprises the step of applying an electrical signal” would be interpreted to mean that the elements
13 of the “apply an electrical signal” step of Claim 8 are added to the elements of the “disposing step”
14 of Claim 1. The Court declines to adopt this interpretation at this time. Claim 8 uses the word
15 “comprises,” which is commonly used to introduce **new** elements. Claim 8 does not use the phrase
16 “further comprises,” which is commonly used to mean that the elements of the dependent claim are
17 being **added to** the elements of the independent claim.²⁰

18 Alternatively, the language of Claim 8 may be interpreted as providing that its elements
19 **replace** the elements of the “disposing step.” Under this interpretation, the phrase “wherein said
20 step of disposing said distal top comprises the step of applying an electrical signal” would be
21 interpreted to mean that the “disposing step” is eliminated and a new step is added, i.e., applying an
22 electrical signal to the tip to form a thrombus. If adopted, this interpretation would render Claim 8
23 arguably indefinite because each dependent claim must contain all of the limitations of its associated
24 independent claim. See 35 U.S.C. § 112. In addition, if Claim 8 is interpreted as replacing the

25
26
27 ²⁰ See Claim 2 of the '136 Patent.

1 “disposing step,” Claim 8 would also be arguably indefinite because an essential element, namely,
 2 inserting the tip into the cavity, would be eliminated.

3 In sum, because of the ambiguity created by the use of the word “comprises” and of the
 4 alternative interpretation described above, the Court finds Claim 8 arguably indefinite and requests
 5 the parties to provide further briefing with respect to the validity of Claim 8.

6 **D. Motion to Establish Priority Date of Patents Based on the ‘211 Application**

7 On February 24, 1992, the inventors filed the 07/840,211 Application (‘211 Application) as a
 8 Continuation-in-Part (CIP) Application to the ‘717 Application. A CIP application is entitled to the
 9 parent’s filing date as to any common subject matter. 35 U.S.C. § 121. In their motion, Defendants
 10 contend that because the specification in the ‘717 Application does not support any occlusion other
 11 than electrothrombosis, claims issued from the ‘211 Application²¹ for methods of occlusion other
 12 than electrothrombosis are not entitled to the priority date of the ‘717 Application.

13 First, the Court finds that this part of Defendants’ motion is improperly noticed. In a single
 14 paragraph, Defendants are attempting to advance a separate motion. Second, the motion is untimely,
 15 because it is contingent on the Court’s ruling that Claims 1-4 of the ‘136 Patent are invalid for
 16 failure to meet the written description requirement for any occlusion other than electrothrombosis.
 17 Accordingly, this part of the Defendants’ motion is DENIED as premature.

18 **IV. CONCLUSION**

19 For the reasons stated above, the construction of Claim 1 of the ‘136 Patent is modified.

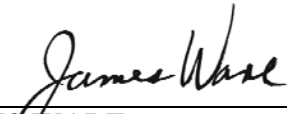
20 Defendants’ Motion for Summary Judgment of Invalidity of Claims 1-4 of the ‘136 Patent is
 21 DENIED without prejudice. Any renewed motion based on the identical invalidity ground shall be
 22 structured in accordance with the issues outlined in this Order.

23
 24
 25 _____
 26 ²¹ Defendants’ motion address the following claims: Claims 11-14, 16-19 of the ‘578
 27 Patent; Claims 1, 4, 5, 6, 7, and 10 of the ‘037 Patent; Claims 1, 2 and 6 of the ‘963 Patent; Claims
 1, 2, 3, 5, 6, 7, and 9 of the ‘126 Patent; Claims 1-6, 8, 10, 16, 20, 25-30, 35, 37, 38 and 42-47 of the
 ‘133 Patent.

1 Finally, the Court finds Claim 8 of the '136 Patent arguably indefinite and directs the parties
2 to address this finding in pretrial motions.

3 This Order does not address the two pending issues remaining in Defendants' motion for
4 summary judgment of invalidity of: (1) all claims that encompass body cavities other than vascular
5 cavities and fluids other than blood for lack of written description; (2) Claim 8 of the '133 Patent for
6 lack of written description and enablement.

7
8 Dated: August 17, 2007



JAMES WARE
United States District Judge

THIS IS TO CERTIFY THAT COPIES OF THIS ORDER HAVE BEEN DELIVERED TO:

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Dated: August 17, 2007

Richard W. Wieking, Clerk

**By: /s/ JW Chambers
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